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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,354	12/31/2003	Gregory Waimong Chan	5618P3473	1158

8791 7590 03/22/2007  
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EXAMINER	
KOHARSKI, CHRISTOPHER	
ART UNIT	PAPER NUMBER
3763	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/749,354

Applicant(s)

CHAN ET AL.

Examiner

Christopher D. Koharski

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3,5-16,19,21-32 and 75-84 is/are pending in the application.
- 4a) Of the above claim(s) 13-16 and 29-32 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3,5-12,19,21-28 and 75-77 is/are allowed.
- 6) ☒ Claim(s) 78 and 82-84 is/are rejected.
- 7) ☒ Claim(s) 79-81 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

Examiner acknowledges the reply filed 1/16/2007, in which claims 5, 8, 21 and 24 were amended. Currently claims 3, 5-16, 19, 21-32 and 75-84 are pending for examination in this application. Currently claims 13-16 and 29-32 are withdrawn from examination.

### ***Allowable Subject Matter***

Claims 3, 5-12, 19, 21-28 and 75-77 are allowed.

Claims 79-81 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims, 78 and 82-84 are rejected under 35 U.S.C 103(a) as being unpatentable over Epstein et al. (6,835,193) in view of Green (6,217,554).

Regarding claims 78 and 82-84, Epstein et al. discloses an injection device comprising an expandable body (42) with at least one delivery cannula with a lumen therethrough with a needle (6) disposed in the lumen with a protuberance defining a sleeve (14) thereon close to the distal delivery end with a first stop (15) and second stop (20) defining a diameter less than the outer diameter of the outer diameter on the protuberance of the needle and located distal and proximal to the protuberance (Figures 3-4) connected to a hub (520) which the needle extends through and is capable of being maintained in a prescribed axial distance orientation (525) (Figures 5-6).

Epstein meets the claim limitations as described above except for an expandable balloon member and differing axial orientation.

However, Green teaches a method and apparatus for delivering substances into extravascular tissue.

Regarding claims 78 and 82-84, Green teaches an injection catheter comprising a cannula member (11), expandable balloon (15), movable needle assembly (28) that is composed of super elastic shape alloys (col 4, ln 5-15), a (Figures 1-3B) needle hub with a protrusion coupled to the distal end of the needles wherein the hub is capable of maintaining the needles is a specific axial depth and radial orientation (Figures 1-3B) of at least 15 degrees (Figures 2A and 3A).

At the time of the invention, it would have been obvious to add the balloon and axial orientation of Green to the system of Epstein et al. because the balloon element

and needle orientation allows for controlled needle injection. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Green.

### ***Response to Arguments***

Applicant's arguments filed 1/16/2007 have been fully considered but they are not persuasive. Applicant's representative asserts that the combination of Epstein et al. in view of Green does not disclose a hub coupled to a proximal portion of a cannula and retaining a needle according to a prescribed radial orientation by a second protuberance on a proximal portion of the needle. Examiner disagrees, the locking mechanism (Figure 1) of Epstein et al. is capable of moving and sustaining the needles (32) in a radial orientation (Figures 2A-3A and 2B-3B), and it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974). Therefore the prior art meets the claim limitation and does not need to implicitly state the maintaining a prescribed radial orientation.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 3/15/07

  
[Faint, illegible text stamp]

  
Christopher D. Koharski  
AU 3763